DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 29, 2014

Advanced Orthopaedic Solutions, Incorporated
Anna Hwang
Regulatory Associate
3203 Kashiwa Street
Torrance, California 90505

Re: K141912
Trade/Device Name: AOS Small External Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: KTT, JDW
Dated: September 12, 2014
Received: September 16, 2014

Dear Ms. Hwang,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141912

Device Name
AOS Small External Fixation System

Indications for Use *(Describe)*
The AOS Small External Fixation System is intended to be used with the AOS External Fixation System. It is intended to be used in the stabilization of open and/or unstable fractures in anatomies such as the hand, wrist, forearm, foot, and ankle where soft tissue injury may preclude the use of other fracture treatments.

The AOS Small External Fixation System is intended to be non-weight bearing.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

ADVANCED ORTHOPAEDIC SOLUTIONS

5. TRADITIONAL 510(K) SUMMARY

DATE PREPARED: September 8, 2014

SUBMITTED BY:
Advanced Orthopaedic Solutions, Inc.
3203 Kashiwa Street
Torrance, CA 90505
Phone: (310) 533-9966

CONTACT PERSON:
Anna Hwang
Advanced Orthopaedic Solutions, Inc.
3203 Kashiwa Street
Torrance, CA 90505
Phone: (310) 533-9966

DEVICE NAME: AOS Small External Fixation System

COMMON NAME: External Fixation

CLASSIFICATION: Class II, 21 CFR 888.3030, Single/Multiple component Metallic Bone Fixation Appliance and Accessories

DEVICE CODE: KTT; JDW

SUBSTANTIALLY EQUIVALENT DEVICES: AOS External Fixation System (510(k): K080408, Cleared April 25, 2008); Stryker Hoffmann II Compact External Fixation System and Hoffmann Fixation Pin System (510(k): K971755/K861766, Cleared July 17, 1997 and July 08, 1986); Hoffmann II Micro External Fixation System, K042019(Cleared September 24, 2004); DePuy Synthes Small External Fixation System (510(k): K122455, Cleared April 11, 2013)

DEVICE DESCRIPTION: The AOS Small External Fixation System is an external fixation device comprised of rods, clamps, and threaded pins used for the management of bone fractures and reconstructive orthopedic surgery. The system is a modular system designed to provide options in frame construction, simplicity in frame components, and ease of use. The AOS Small External Fixation System is manufactured with threaded half pins and rods of 5.0mm shaft diameter, which allows for connectivity with AOS' External Fixation System (510(k) cleared: K080408) for support with bone fractures. The system is comprised of titanium and stainless steel (pin-to-rod and multi-pin) clamps, stainless steel threaded half pins and k-wires, carbon fiber connector rods, and pin caps. The AOS Small

External Fixation System is a non-sterile single use fixation device.

The pin-to-rod clamps are designed to clamp to the 5.0mm carbon fiber rods and to the 2.0mm and 3.0mm stainless steel pins. The multi-pin clamps are designed to stabilize fractures using multiple pins in close proximity to each other. The multi-pin clamps can be used individually or as part of a larger construct.

The stainless steel threaded pins come in thread diameters of 2.0mm and 3.0mm with a 5.0mm shaft diameter. Thread lengths are available in 5mm increments from 10mm to 25mm long. Overall pin lengths of 55mm, 75mm, 100mm and 140mm are available. The stainless steel k-wires are provided in a 1.5mm diameter.

The connecting rods are carbon fiber composite with an diameter of 5.0mm and are in lengths of 50mm, 75mm, 100mm, 125mm, 150mm, 200mm, 250mm, and 300mm.

The surgical technique used for the AOS Small External Fixation System is a standard method used for external fixation and is the same as the technique used for the predicate devices. The instrumentation for the system consists of a wrench, two T-wrenches, a drill guide, and drills.

INDICATIONS FOR USE:

The AOS Small External Fixation System is intended to be used with the AOS External Fixation System. It is intended to be used in the stabilization of open and/or unstable fractures in anatomies such as the hand, wrist, forearm, foot, and ankle where the soft tissue injury may preclude the use of other fracture treatments. The AOS Small External Fixation System is intended to be non-weight bearing.

SUBSTANTIAL EQUIVALENCE:

Information presented supports substantial equivalence of the AOS Small External Fixation System due to the similarity in indication for use, design features, operating principles, and material of composition to the AOS External Fixation System, K080408; Stryker Hoffmann II Compact External Fixation System and Hoffmann Fixation Pin System K971755/K861766; Hoffmann II Micro External Fixation System, K042019; and DePuy Synthes Small External Fixation System, K122455.

The construct of the AOS Small External Fixation System and the predicate devices are virtually identical. Since the devices are substantially equivalent in design, geometry, construction, materials of construction, and indications, it was determined that no mechanical testing was necessary to demonstrate substantial equivalence.